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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,911	08/10/2000	Badri N. Prasad	6759	6357

25763 7590 12/19/2003

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,911

Applicant(s)

PRASAD ET AL.

Examiner

Carolyn M Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the restriction requirement filed 31 October 2003. Claims 1-47 are pending. Claims 48-83 are withdrawn from consideration. The IDS statements filed 26 February 2001 and 25 April 2003 have been entered and considered.

Election/Restrictions

2. At page 1 of the response filed 31 October 2003 (paper number 5), Applicant affirms the election of Group I (claims 1-47) for prosecution. In response, it is noted that no arguments were present to traverse the restriction, and therefore Group II (Claims 48-83) are withdrawn from consideration in the present application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15, 25-26, 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(A) Claim 15, line 3, "the group" lacks proper antecedent basis. For purposes of applying prior art, claim 15 is being interpreted as "the plurality of weights is the average incremental cost associated with each of the plurality of disease classes".

(B) As per claims 25-26, line 3, "the average incremental cost associated with the group for a benchmark population" and "the average incremental cost for the group during the base period" lack proper antecedent basis. For purposes of applying prior art, claims 25-26 are being interpreted as a predetermined weight factor is based on a cost.

(C) Claim 39, line 2, "the computed score" lacks proper antecedent basis. It is unclear to the Examiner how the "computed score" exists when the computing step has yet to be performed. For purposes of applying prior art, claim 39 is being interpreted as the step of calibrating a model.

(D) Claims 40-42 depend on claim 39 and are therefore rejected for the same reasons given for claim 39, and incorporated herein.

(E) Claim 43, line 2, "the computed score" lacks proper antecedent basis. It is unclear to the Examiner how the "computed score" exists when the computing step has yet to be performed. For purposes of applying prior art, claim 43 is being interpreted as the step of calibrating a model.

(F) Claims 44-46 depend on claim 43 and are therefore rejected for the same reasons given for claim 43, and incorporated herein.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

(A) For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example), and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the process must somehow apply, involve, use, or advance the technological arts.

In the present case, claim 1 only recites an abstract idea. The recited steps of merely calculating a burden of illness for the member based on the plurality of provider claims, wherein the burden of illness is a number, and computing a score for the member based on the burden of illness and at least one explanatory variable do not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to model the utilization of healthcare resources.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention computes a score for a member (i.e., repeatable) to model healthcare utilization (i.e., useful and tangible).

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention as a whole, is not within the technological arts as explained above, claim 1 is deemed to be directed to non-statutory subject matter.

(B) Claims 2-47 inherit the above deficiencies through dependency, and are thus rejected for the same reasons provided for claim 1, and incorporated herein.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-7, 9, 11, 14-16, 18-21, 23-24, 25-32, 35-37, and 39-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (5,976,082).

(A) As per claim 1, Wong discloses a method for generating a model of adverse health outcomes resulting in substantial use of health care resources (e.g., funds), wherein the model is based on an events window (reads on "base period") and generated by extracting health care claims of benefit providers for reimbursement, wherein the model predicts use of health care resources for a prediction region (reads on "target period") (Figures 2-3, 6A-6B, Abstract, col. 4 line 60 to col. 5 line 40, col. 5 line 50 to col. 6 line 32):

(a) calculating the value of independent variables which represent potential predictors of adverse health outcomes, thus resulting in substantial use of health care resources (e.g., funds), wherein the independent variables include age, gender, HMO membership, site of first CHF diagnosis (site code), ischemic heart disease, diabetes, adverse lifestyle diagnoses, number of Co-Morbid diseases, number of ACE inhibitor prescriptions, number of physician office visits, total costs (in-patient hospital costs, emergency room costs, doctor costs, and pharmacy costs), wherein the some of the independent variables range from 0-X, wherein the values of the independent variables are based on health care claims of patients (Figures 2-5, col. 4 line 60 to col. 5 line 65,

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col. 7 line 21 to col. 8 line 22, col. 12 line 23 to col. 13 line 50, col. 14 line 59 to col. 15 line 13, col. 17 line 49 to col. 18 line 50) (It is noted the independent variables listed at col. 12 in Table 1 are used as predictors in the prediction model

$\text{Logit}(p) = a + bx_1 + cx_2 \dots z_{xi}$ (see col. 14 line 59 to col. 15 line 13) to calculate the value of $\text{Logit}(p)$ (reads on "burden of illness is a number")); and

(b) calculating an individual's probability (p) for the outcome under consideration, such as predicting an adverse health outcome, wherein the calculation is based on the value of $\text{Logit}(p)$ using the independent variables as discussed in part (a), wherein the $p = e^{-\text{Logit}(p)} / (1 + e^{-\text{Logit}(p)})$ (Figures 2-5, col. 4 line 60 to col. 5 line 65, col. 7 line 21 to col. 8 line 22, col. 12 line 23 to col. 13 line 50, col. 14 line 59 to col. 15 line 13, col. 17 line 49 to col. 18 line 50).

(B) As per claims 2-4, Wong discloses using claims from doctors, hospitals, and pharmacies (Figures 2-5, col. 3 lines 49-56, col. 5 lines 55-65).

(C) As per claim 5, Wong discloses performing preprocessing steps including processing, based on predetermined criteria, the patient information in the claims database to extract claims information for a group of patients, wherein the criteria includes extracting patients having been diagnoses with congestive heart failure or prescribed an anti-CHF drug, wherein the patient information extracted is used in generating the prediction model and calculating the individual's probability (p) for the outcome under consideration, wherein the model is based on an events window (reads

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on "base period") and generated by extracting health care claims of benefit providers for reimbursement from the events window time interval (reads on "target period"), wherein the model predicts use of health care resources for a prediction region based on the time interval (Figures 1A, 2-5, col. 3 line 60 to col. 4 line 33, col. 6 line 64 to col. 7 line 64, col. 13 line 47 to col. 14 line 59, col. 17 line 49 to col. 18 line 50).

(D) As per claim 6, Wong discloses cleaning data and performing quality checks by using threshold values to check whether an imbalance exists in the data, whether claims need to be rejected, or if multiple claims exist (col. 3 line 40 to col. 4 line 44, col. 6 lines 32-45, col. 8 lines 23-35).

(E) As per claim 7, Wong discloses assigning prescribed medications including the drug codes into drug therapeutic classes (Figures 2-5, col. 7 lines 37-47, col. 11 lines 14-68).

(F) As per claim 9, Wong discloses multiplying each of the independent variables, such as ischemic heart disease, cardiac dysrhythmias, hypertensive disease, number of co-morbid diseases, number of CHF hospitalizations, number of CHF emergency services, number of physician office visits, number of ACE inhibitor prescriptions, number of digoxin prescriptions (reads on "therapeutic pharmacy classes"), and number of loop diuretic prescriptions, by a parameter estimate and then summing the independent

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variables times the parameter estimates to calculate a value (reads on "burden of illness") (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(G) As per claims 11 and 14, Wong discloses assigning diseases having ICD-9 codes into a plurality of sub classes (col. 9 line 45 to col. 10 line 31) and summing the independent variables or values for the sub classes multiplied by the parameter estimates to calculate a value (reads on "burden of illness") (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(H) As per claim 15, Wong discloses the parameter estimates including the total costs, in-patient hospital costs, emergency room costs, doctor costs, cardiovascular costs, and CHF costs, wherein the costs are associated with an ICD-9 code (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(I) As per claim 16, Wong discloses assigning claims having ICD-9 codes and a site code into a plurality of sub classes, wherein the site codes include codes for determining whether a claim was an ER visit, Office Visit, or Hospitalization, and wherein the ICD-9 codes include descriptions such as acute myocardial infarction and angina pectoris (reads on "medical episode") (Figures 2-5, col. 7 lines 37-47, col. 9 line 5 to col. 10 line 31).

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(J) As per claim 18, assigning pharmacy claims to a sub class based on the medical claims (Figures 2-5, col. 7 lines 37-47, col. 9 line 5 to col. 10 line 31).

(K) Claim 19 repeats the same limitations as claim 4, and is therefore rejected for the same reasons given for claim 4, and incorporated herein.

(L) As per claim 20, Wong discloses multiplying each of the independent variables, such as ischemic heart disease, cardiac dysrhythmias, hypertensive disease, number of co-morbid diseases, number of CHF hospitalizations, number of CHF emergency services, number of physician office visits, by a parameter estimate and then summing the independent variables times the parameter estimates to calculate a value (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(M) As per claim 21, Wong discloses the parameter estimates including a parameter estimate based on the number of co-morbid diseases found in the claims (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(N) As per claim 23, Wong discloses the parameter estimates including a parameter estimate based on the age of the member found in the claims (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

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(O) As per claim 24, Wong discloses the parameter estimates including a parameter estimate based on the gender of the member found in the claims (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(P) As per claims 25-26, Wong discloses a parameter estimate relating to the cost of in-patient hospital costs, emergency room costs, doctor costs, and pharmacy costs (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(Q) As per claim 27, Wong discloses an independent variable being the age of the patient based on the claims for the patient (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(R) As per claim 28, Wong discloses an independent variable being the gender of the patient based on the claims for the patient (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(S) As per claim 29, Wong discloses an independent variable relating to a particular diagnosis, namely, congestive heart failure (col. 7 lines 20-30, col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(T) As per claim 30, Wong discloses an independent variable being the number of ACE inhibitor prescriptions, number of digoxin prescriptions, number of loop diuretic

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prescriptions, and number of other CV prescriptions based on the claims for the patient (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(U) As per claims 31-32, Wong discloses independent variables relating to the number of office visits, hospitalizations, and ER visits and total costs (in-patient hospital costs, emergency room costs, doctor costs, and pharmacy costs) (Figure 4, col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33). It is noted that tracking the numbers for visits from claims is a form of "recency of claims for the member".

(V) As per claim 35, Wong discloses calculating an individual's probability (p) for the outcome under consideration, such as predicting an adverse health outcome, wherein the calculation is based on the value of $\text{Logit}(p)$ using the independent variables as discussed in part (a), wherein the $p = e^{-\text{Logit}(p)} / (1 + e^{-\text{Logit}(p)})$ for a particular patient having HMO membership (Figures 2-5, col. 4 line 60 to col. 5 line 65, col. 7 line 21 to col. 8 line 22, col. 12 line 23 to col. 13 line 50, col. 14 line 59 to col. 15 line 13, col. 17 line 49 to col. 18 line 50).

(W) Claim 36 repeats the same limitations as claim 3, and is therefore rejected for the same reasons given for claim 3, and incorporated herein.

(X) As per claim 37, Wong discloses identifying patients having a high risk of an adverse health outcome such as the top 5% or 10% of the patients (col. 15 lines 40-55).

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(Y) As per claims 39 and 43, Wong discloses a step of performing a quality check on the data to make sure that the prediction model is not unreasonably skewed due to imbalanced input information (col. 8 lines 23-35) and a step of updating the model by repeating the entire process of generating the model and probability to determine if other variables are better predictors (col. 15 lines 40-54).

(Z) Claims 40-42 and 44-46 repeat the same limitations as claims 2-4, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8, 10, 12-13, 17, 38, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1.

(A) As per claim 8, Wong fails to expressly disclose using GC3 therapeutic pharmacy classes. However, Wong discloses assigning prescribed medications including the drug codes into drug therapeutic classes, specifically DM therapeutic class codes (Figures 2-5, col. 7 lines 37-47, col. 11 lines 14-68, Appendix III). It is respectfully submitted that

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the skilled artisan could use another form of classes other than DM class codes as disclosed by Wong. The motivation being to provide a flexible coding system when generating models thus increasing the usefulness of the models.

(B) As per claim 10, Wong discloses multiplying each of the independent variables, such as ischemic heart disease, cardiac dysrhythmias, hypertensive disease, number of co-morbid diseases, number of CHF hospitalizations, number of CHF emergency services, number of physician office visits, number of ACE inhibitor prescriptions, number of digoxin prescriptions (reads on "therapeutic pharmacy classes"), and number of loop diuretic prescriptions, by a parameter estimate and then summing the independent variables times the parameter estimates to calculate a value (reads on "burden of illness") (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33). Wong fails to expressly disclose summing a plurality of weights corresponding to relevant combinations of therapeutic pharmacy classes present for the member. However, it is respectfully submitted that when generating models typically the interactions of different variables are examined, and the skilled artisan would have found it an obvious modification to the method of Wong to include combinations of therapeutic pharmacy classes with the motivation of providing the most accurate model for the prediction of adverse health outcomes (Wong; col. 12 lines 27-31).

(C) As per claims 12-13, Wong discloses using ICD-9 codes and therapeutic classes to assign diseases into appropriate subclasses (col. 6 lines 17-32, col. 9 lines 43-63).

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Although Wong fails to expressly recite CCG classes or categories, it is respectfully submitted that the skilled artisan could use another form of classes other than ICD-9 class codes as disclosed by Wong. The motivation being to provide a flexible coding system when generating models thus increasing the usefulness of the models.

(D) As per claim 17, Wong fails to expressly disclose Clinical Care Groups. However, Wong suggests using sub-classes (col. 9 lines 50-61). It is respectfully submitted that using a specific grouping (i.e. Clinical Care Groups) is another form of grouping. The skilled artisan would have it obvious to include another grouping schema within the method of Wong. The motivation being to provide a flexible grouping system when generating models thus increasing the usefulness of the models.

(E) As per claim 38, Wong discloses using claims from doctors, hospitals, and pharmacies (Figures 2-5, col. 3 lines 49-56, col. 5 lines 55-65). Although Wong does not expressly disclose calculating a second score based on information in both the pharmacy claims and the medical claims, it is respectfully submitted that using both sets of claims would have been an obvious modification to Wong with the motivation of ensuring the accuracy of the model.

(F) As per claim 47, Wong discloses a step of performing a quality check on the data to make sure that the prediction model is not unreasonably skewed due to imbalanced input information (col. 8 lines 23-35) and a step of updating the model by repeating the

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entire process of generating the model and probability to determine if other variables are better predictors (col. 15 lines 40-54). Although Wong fails to expressly recite comparing the calculated burden of illness against healthcare utilization for a known target period, it is respectfully submitted that typically in model generation, the model is compared with a baseline to determine if the model is correct. Thus, the skilled artisan would have found it an obvious modification within the method of Wong to include calibrating the model with the motivation of ensuring the accuracy of the model.

11. Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1, and further in view of Mohlenbrock et al. (5,018,067).

(A) As per claim 22, the teachings of Wong in the rejections above are incorporated herein.

Wong fails to teach the predetermined weight factor being adjusted based on the presence of a co-morbidity for the group or complication for the group of claims.

Mohlenbrock discloses the weights assigned to diagnostic codes which have a cc status, wherein cc relates to complication or co-morbidity (col. 13 lines 10-66).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned features of Mohlenbrock within the method of Wong with the motivation of considering the severity of illness of patients (Mohlenbrock; col. 13 lines 55-61).

12. Claims 33-34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1, and further in view of Lockwood (5,706,441).

(A) As per claims 33-34, the teachings of Wong in the rejections above are incorporated herein.

Wong fails to expressly disclose calculating a relative risk for the member of a group by dividing the score by an average score for the group or by dividing the score by an average score for a benchmark group.

Lockwood discloses comparing the severity scores for sickness episodes against benchmarks by dividing the scores with the benchmarks and comparing a score by the average score for a group (col. 11 line 44 to col. 13 line 41).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to combine the teachings of Lockwood within the method of Wong with the motivation of identifying and assessing high risk patients (Wong; col. 2 lines 38-45).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches an apparatus and method for categorizing health care utilization (5,486,999), method and system for

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generating statistically-based medical provider utilization profiles (5,557,514 and 6,223,164), method and apparatus for objectively monitoring and assessing the performance of health-care providers (5,706,441 and 5,845,254), health care payment system utilizing an intensity adjustment factor applied to provider episodes of care (5,819,228), techniques for estimating charges of delivering healthcare services that take complicating factors into account (6,061,657), risk adjustment tools for analyzing patient electronic discharge records (6,266,645), and an article on the burden of illness in Canada (www.burdenofillness.ca).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

15. **Any response to this action should be mailed to:**

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Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 or (703) 872-9326 [Official communications]

(703) 872-9327 [After Final communications labeled "Box AF"]

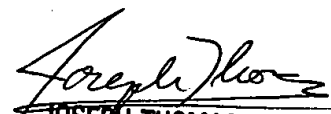
(703) 746-8374 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive,
Arlington, VA, 7th Floor (Receptionist).



CB

December 10, 2003


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600